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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,713	11/10/2003	Guenter Frey	RDID 02106US (WP21455)	6392
7590 07/24/2007				
Brent A. Harris Roche Diagnostics Corporation Bldg. D 9115 Hague Road Indianapolis, IN 46250			EXAMINER HYUN, PAUL SANG HWA	
			ART UNIT 1743	PAPER NUMBER
			MAIL DATE 07/24/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/705,713	<b>Applicant(s)</b> FREY ET AL.	
	<b>Examiner</b> Paul S. Hyun	<b>Art Unit</b> 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 8 May 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8-19 and 22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-19 and 22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 November 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***REMARKS***

In response to the Office action dated 12/26/06, Applicants amended claims 1, 10 and 12 and cancelled claim 7. In summary claims 1-6, 8-19 and 22 remain pending.

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "trigger unit" recited in claim 6 must be shown or the feature canceled from the claims. There is nothing in the drawings that resembles a trigger. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims **1-4, 8-12, 14-16 and 18** are rejected under 35 U.S.C. 102(b) as being anticipated by Ogura et al. (US 5,364,533).

Ogura et al. disclose a device for isolating plasma from a blood sample as well as the method for using the device to isolate plasma (see Figs. 9 and 10).

The device comprises a first zone comprising a separation fleece 24 and a second zone comprising a transport fleece 29 wherein the first zone is accessible for blood application and the second zone is positioned in a movable holder 28. The separation fleece 24 is selectively permeable to plasma and thus separates the plasma from rest of the blood sample. The device also comprises a discharge unit 23b that applied pressure to facilitate the separation and the discharge of the plasma via outlet 28a. The discharge unit applies pressure on the second zone 29 in a direction perpendicular to the plane of the second zone without appearing to affect the first zone. The reference also discloses a means and a method for measuring the constituents of the separated plasma (e.g. glucose, GPT, etc), (see columns 5 and 6).

With respect to claim 8, it should be noted that the claim merely recites an action. The claim does not further limit the invention recited in claim 1.

Claims 1, 2, 4, 6, 9-14, 16, 18, 19 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Kloefer (US 4,883,764).

Kloefer discloses a test strip and a method for using the test strip to separate plasma from whole blood. The test strip comprises a separation member 16 and a recipient member 20. To separate plasma from whole blood, a volume of blood, which can be as little as a droplet (see lines 12-22, col. 9), is applied to the separation member 16. When the blood sample is applied, it flows down the test strip toward an outlet via capillary action, but whole blood is retained in the separation member 16. Once the separation is completed, the separation member is cut from the test strip to prevent contamination and the separated plasma is eluted from the recipient member 20 using a discharge unit in the form of a buffer solution (see lines 20-40, col. 7). The separated plasma can also be subjected to analysis for detecting analytes (see lines 25-35, col. 8), such as apolipoproteins (see lines 1-5, col. 11).

With respect to claim 19, although the reference does not explicitly disclose the metric volume of the blood sample applied to the test strip, it is evident that a droplet of blood is within the range of the volume recited in the claim.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ogura et al.

Ogura et al. disclose the use of a syringe situated at the top of the fleece to apply positive pressure to separate plasma. However, it would have been obvious to one of ordinary skill in the art to position the syringe at the bottom of the fleece and utilize negative pressure to separate plasma if one desires a pulling motion rather than a pushing motion to actuate the plunger of a syringe.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kloepper.

Although the reference does not disclose that the detachment of the separation member and the recipient member is accomplished by a rotating movement, the reference discloses that the separation member and the recipient member are separated by a scored perforation (see lines 45-60, col. 7). It is well known in the art to

rip a perforated score line by applying a torque/rotating motion. Therefore, it is apparent or obvious that the test strip disclosed by Kloefer is configured to rotate about 90 degrees.

### ***Response to Arguments***

Applicant's arguments with respect to the claims have been considered but are moot in view of the new grounds of rejection. The amendment to the claims necessitated new grounds of rejection. Nonetheless, Applicants' arguments that are relevant to the cited references will be addressed. Specifically, it should be noted that the limitation "without the discharge unit having an effect on the first zone" recited in claims 1 and 10 was interpreted broadly as possible within reason. The claims and the Specification do not define the scope of the limitation "effect".

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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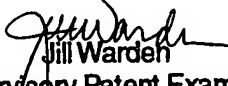
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul S. Hyun whose telephone number is (571)-272-8559. The examiner can normally be reached on Monday-Friday 8AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PSH  
7/13/07

  
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